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| APPLICATION NO.   | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.               | CONFIRMATION NO. |
|---|-------------|----------------------|-----------------------------------|------------------|
| 10/040,908  | 01/07/2002  | Francis C. Kowalik   | EIP-5809 (99-6624) (1417          | 8904             |
| 7590 05/13/2004   |             |                      |                                   |                  |
| Wallenstein & Wagner, Ltd.<br>53rd Floor<br>311 S. Wacker Drive<br>Chicago, IL 60606-6622 |             |                      | EXAMINER<br>TYLER, CHERYL JACKSON |                  |
|   |             |                      | ART UNIT<br>3746                  | PAPER NUMBER     |

DATE MAILED: 05/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                      |                                       |  |
|------------------------------|--------------------------------------|---------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/040,908 | <b>Applicant(s)</b><br>KOWALIK ET AL. |  |
|                              | <b>Examiner</b><br>Cheryl J. Tyler   | <b>Art Unit</b><br>3746               |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 02 March 2004.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-58 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6, 14, 19, 21, 24, 30, 37, 39, 43, 46-50, 52, 53, 55 and 58 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2004 is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>continued</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 5,7-13,15-18,20,22,23,25-29,31-36,38,40-42,44,45,51,54,56 and 57.

Information Disclosure Statements:  
11/10/2003; 1/14/2004; 2/26/2004

**FINAL ACTION**

***Information Disclosure Statement***

1. The Information Disclosure Statement filed 1/14/2004 only includes the first two sheets. Sheets 3-5 are not included, and should be resubmitted.

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 1, 39, 47, and 53 are rejected under 35 U.S.C. 102(e) as being anticipated by Fowler et al. (6,461,323). Fowler et al. teach tubing 23, 25 (corresponding to the claimed lineset) having a first end capable of attachment to a bag 18 (corresponding to the claimed reservoir) and a second end capable of attachment to a control valve 32 (corresponding to the claimed another component); a pump 20, preferably disposable (see column 4, line 17), for engaging the tubing and controlling a fluid flow through the tubing; batteries 7 (corresponding to the claimed power supply) affixed to a component of the infusion system other than the pump 20 (see Figure 4) and capable of operative connection with the pump. Fowler et al. further teach that the batteries “are removed by ‘cracking open’ the battery housing” (column 4, lines 17-18).

Thus, Fowler et al. teach that the batteries are disposable. Fowler et al. further teach that a switch Sp opens and closes the electrical circuit between battery 7 and motor M (see column 4, lines 40-54). Additionally, as illustrated in Figure 4, the battery housing 84 containing batteries 85, 87 are physically attached to motor M (corresponding to the claimed component of the infusion system other than the durable pump component).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

5. Claims 2-3, 19, 30, 43, 48-50, 53 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler et al. (mentioned previously). Fowler et al. teach a medical infusion system having all of the features claimed except for the specifically affixing the power supply to the tubing. Although the power supply is not located directly to the tubing, it would have been obvious to one of ordinary skill in the art to affix the power supply to the tubing since it was known in the art at the time that affixing the power supply directly to the tubing would reduce the overall size of the pump, and thus, make the unit less cumbersome to transport.

6. Claims 4 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler et al. (mentioned previously) in view of Knighton et al. (6,551,280). Fowler et al. teach most of the limitations of the claims, including a vacuum source. However, Fowler et al. do not explicitly teach that the vacuum source may be a pump. Knighton et al. teach that it is old and well known that a "vacuum can be applied by means of various pumps, aspirators, and suction devices" (column 4, lines 64-65). One of ordinary skill in the art would have known to use a vacuum pump in order to supply a constant vacuum to a device. Therefore, it would have been obvious to one of ordinary skill in the art to use a vacuum pump, as taught by Knighton, in the Fowler et al. invention in order to advantageously provide a constant vacuum to the device.

7. Claims 6, 14, 21, 24, 37, 46, 52, 55, and 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler et al. (mentioned previously) in view of Chen et al. (6,454,789). Fowler et al. teach most of the limitations of the claims. However, they do not explicitly teach the use of low temperature fuel cells. Chen et al. teach "It should be readily apparent to one skilled in the art, based on the instant disclosure, to alternatively use the following items in addition to or in place of their respective presently shown components ... rechargeable battery pack 14, one may use ... rechargeable batteries, or fuel cells, ... Such a power source should preferably operate at a relatively low or ambient temperature" (column 6, line 62 - column 7, line 9). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use low-temperature fuel cells, as taught by Chen et al., in the Fowler et al. invention, in order to

incorporate a reusable power source that would not excessively heat the fluid flowing through the tubing.

8. Claims 6, 21, 52, and 55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fowler et al. (mentioned previously) in view of Saravia et al. (6,106,494). Fowler et al. teach most of the limitations of the claims, except that the batteries may be replaced with fuel cells. Saravia et al. teach a fluid management pump system having a battery pack 26 powering a pump 22. According to Saravia et al., "it should likewise be recognized that the power pack 26 may have other energy providing cells than the described batteries 126... Alternatively, the power pack may have rechargeable fuel cells. These cells, once the power in them is discharged, are recharged by refueling the chemical solution contained therein with a fresh solution" (column 16, lines 22-29). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use a fuel cell, as taught by Saravia et al., in the Fowler et al. invention, in order to advantageously have a renewable source of power which ultimately would reduce the operational costs of using the system.

### ***Response to Arguments***

9. Applicant's arguments filed March 2, 2004 have been fully considered but they are not persuasive. The applicant argues that the Fowler et al. reference does not teach the claimed invention because inter alia the Fowler et al. pump is disposable and

not durable. The definition of “durable” is being “capable of withstanding wear and tear or decay,”<sup>1</sup> of which the Fowler et al. pump is capable.

The applicant further argues that the dictionary definition of “affix” is to “to attach physically” or “fasten to.” The Examiner further consulted multiple dictionaries for the definition of “affix,” and each cite that “affix” means “to secure to something; attach,”<sup>2</sup> which is somewhat broader than the applicant’s definition. Nevertheless, as clearly illustrated in Figure 4, the batteries 85, 87 are “physically attached” to the motor 80, which is a component of the infusion system “other than the durable pump component.” Thus, the rejections are proper and remain.

With regards to the argument that the Fowler et al. pump does not include a lineset, the Examiner respectfully disagrees. The lineset is defined in the applicant’s specification as “tubing having first and second ends” (specification, page 3, lines 27-28), and thus, the “lineset” is clearly taught by Fowler et al. (see Figure 1 and column 3, lines 63-65).

In response to applicant’s arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir.

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1986). The applicant's arguments regarding the 35 U.S.C. 103 rejections are not clearly understood. The Knighton, Chen et al., and Saravia et al. references were cited as obvious modifications of the Fowler et al. reference, and as a base reference for the entire rejection. Each rejection includes a clearly formulated motivation why one of ordinary skill in the art would have known to modify the Fowler et al. reference to arrive at the claimed invention. As, such these rejections too, are proper and remain.

### ***Conclusion***

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

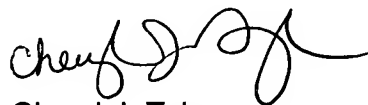
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

***Contact Information***

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl J. Tyler whose telephone number is 703-306-2772. The examiner can normally be reached on Monday-Thursday, 6:00 - 10:30 am.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine R. Yu can be reached on 703-308-2675. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Cheryl J. Tyler  
Primary Examiner  
Art Unit 3746

CJT